

Patent claims

1. Pharmaceutical product for injection comprising a container including a closure suitable for preparations for injection, the container containing a compound selected from the group of an acid labile proton pump inhibitor, a salt thereof, a solvate of an acid labile proton pump inhibitor and a salt thereof, wherein the container and closure are made of material which essentially does not release zinc ions.
2. Pharmaceutical product according to claim 1 containing a compound selected from the group of 5-difluoromethoxy-2-[(3,4-dimethoxy-2-pyridinyl)methylsulfinyl]-1H-benzimidazole (pantoprazole), a salt thereof, a solvate of pantoprazole and a salt thereof.
3. Pharmaceutical product according to claim 2, wherein pantoprazole is pantoprazole sodium sesquihydrate.
4. Pharmaceutical product according to claim 1, containing omeprazole magnesium, omeprazole, esomeprazole magnesium or esomeprazole.
5. Product according to claim 1, wherein the closure is made of material wherein the amount of extractable zinc is equal or less than 5 ppm, equal or less than 4 ppm, more preferred equal or less than 3 ppm, even more preferred equal or less than 1 ppm and most preferred 0 ppm (i.e. not detectable) of extractable zinc, when determined according to European Pharmacopoeia 2002.
6. Product according to claim 5, wherein the closure is a butyl rubber stopper of type 1 according to European Pharmacopoeia 2002, which is partially fluoro-polymer laminated.
7. Product according to claim 1, comprising a clear glass vial fitted with a rubber stopper of type 1 according to European Pharmacopoeia 2002 and a crimp seal.
8. Product according to claim 7, wherein the rubber stopper is a stopper according to claim 6.
9. Product according to claim 7, wherein the glass vial comprises a blow back inside the flange, and the closure is a butyl rubber stopper of type 1 according to European Pharmacopoeia 2002 having 0 ppm of extractable zinc, which stopper is partially fluoro-polymer laminated.

10. Product according to claim 9, wherein the fluoro-polymer lamination extends from the area of the stopper surface following the area of the stopper which is contacting the blow back inside the flange of the vial downwards and covers those parts of the stopper which extend inside the vial.
11. Product according to claim 1, having reduced pressure inside the container.
12. Product according to claim 11, wherein the reduced pressure is 800 mbar or below, 600 mbar or below or 500 mbar or below.
13. Product according to claim 1, having a volume of 20 ml or less.
14. Product according to claim 1, additionally containing one or more suitable excipients.
15. Product according to claim 14, wherein the excipients are selected from the group of complexing agents, stabilizers, suitable bases, carriers and mixtures thereof.
16. Product according to claim 14, comprising ethylenediamine tetraacetic acid and/or a suitable salt thereof and sodium hydroxide.
17. Process for manufacturing a pharmaceutical product for injection according to claim 1 comprising the steps of (a) providing a mixture of the acid labile proton pump inhibitor with a solvent and optionally further excipients in the container (b) subjecting the container comprising the above mixture to freeze drying and (c) closing the container with the closure.
18. Process according to claim 17, wherein step (c) is affected under reduced pressure.
19. Method for the treatment of or prevention of a stomach disorder wherein a product according to claim 1 is employed.
20. Method of treatment or prophylaxis of a disease selected from the group of benign gastric ulcer, gastroesophageal reflux disease (GERD), GERD associated with a history of erosive esophagitis, pathological hypersecretion associated with Zollinger-Ellison Syndrome, Zollinger-Ellison syndrome, duodenal ulcer, duodenal ulcer associated with *Helicobacter pylori*, prophylaxis of NSAID-associated gastric or duodenal ulcer in patients with an increased risk of gastroduodenal complication who require continued NSAID treatment and combination therapy with antibiotics in the eradication of *Helicobacter pylori* wherein a product according to claim 1 is employed.